

## **REMARKS/ARGUMENTS**

The preceding amendments and following remarks are submitted in response to the non-final Office Action mailed October 13, 2005, setting a three month shortened statutory response ending January 13, 2006. With this Amendment, claims 1-11, 13-26 and 28-30 have been amended, claims 12 and 27 have been cancelled, and claims 49-55 have been added. Claims 1-11, 13-26, and 28-55 remain pending in this Application. Reconsideration, examination and allowance of all pending claims are respectfully requested.

### **35 U.S.C. § 112 ¶ 2 Rejections**

On page 1 of the Office Action, the Examiner rejected claims 1-30 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner states that a tubular insertable apparatus is recited in the base claim whereas an extracorporeal element is claimed apart from the apparatus. In addition, the Examiner states that it is unclear whether a transducer portion is being claimed, and that the ultrasound transducer unit could be interpreted as being at least partly extracorporeal.

With this Amendment, Applicant has amended the preamble of claims 1-11, 13-26 and 28-30 substituting the phrase “tubular apparatus insertable within the body” with the phrase “medical assembly”. Applicant asserts that these amendments overcome the Examiner’s rejections under 35 U.S.C. § 112, second paragraph.

### **35 U.S.C. § 103(a) Rejections**

On page 2 of the Office Action, the Examiner rejected claims 1-48 under 35 U.S.C. § 103(a) as being unpatentable over *Daikuzono* (U.S. Patent No. 5,623,940) or

*Shturman* (U.S. Patent No. 5,331,947), in either case further in view of *Lipscher et al.* (U.S. Patent No. 5,785,051).

Applicant respectfully asserts that claims 1-48 are not obvious in view of either *Daikuzono* or *Shturman* in further view of *Lipscher et al.* The *Daikuzono* reference appears to disclose a catheter apparatus having a sensor which is insertable within the rectum in combination with a laser balloon catheter which is insertable into the urethra for conducting laser treatment on the prostrata (64). The laser balloon catheter, which as shown in Figure 5 is a separate catheter from the sensing catheter apparatus (70), includes a number of balloons (1,2) for cooling the prostrata (64) during laser treatment. In one embodiment depicted in Figure 16, the catheter apparatus (70) includes a distal end portion equipped with an ultrasonic probe (92) for detected changes in the position of the prostrate (64).

During operation, a biasing balloon (76) located opposite the ultrasonic probe (92) is inflated with air, causing the ultrasonic probe to engage the inner wall of the rectum (68). Ultrasonic waves emitted from the ultrasonic probe (92) at a location within the rectum (68) are reflected against the prostrata (64), which are then received back at the ultrasonic probe (92). As can be clearly understood by reference to Figures 5 and 16, the transducer portion of the ultrasonic probe (92) is located within the body towards the end of the catheter apparatus (70), and does not direct ultrasonic waves through either of the balloons (1,2).

The *Shturman* reference, in turn, appears to disclose an ultrasound catheter (20) that can be positioned within an inflatable sheath (30) extending through a fiber optic endoscope (40). As can be seen in Figure 8, the distal portion (26) of the ultrasonic

catheter (20) includes an ultrasonic transducer element (22) that emits ultrasonic waves through a sonoluent coupling fluid medium inside the distal portion (32) of the inflatable sheath (30), allowing the ultrasound transducer element (22) to scan the tissue adjacent to the expanded sheath (30). As with the ultrasonic probe (92) in *Daikuzono*, the ultrasonic transducer element (22) described in the *Shturman* reference is similarly located within the body towards the distal portion (26) of the ultrasonic catheter (20).

The *Lipscher et al.* reference appears to disclose an endotracheal apparatus (100) including a tube (101) having a first ultrasonic transducer means (103) attached near its distal end (102) for transmitting ultrasonic waves within the trachea, and a second ultrasonic transducer means (105) for receiving the ultrasound waves transmitted by the first ultrasonic transducer means (103). As shown in one embodiment in Figure 2B, the endotracheal apparatus (200) includes an ultrasound transducer (218) having a number of piezoelectric ultrasound elements (219) coupled to a balloon cuff (215) that, when inflated, urges the elements (219) into intimate contact with the forward inner wall of the patient's trachea.

Unlike the *Daikuzono*, *Shturman*, and *Lipscher et al.* references, amended independent claims 1 and 16 each recite a medical assembly including at least one extracorporeal ultrasound transducer for ultrasonically placing and monitoring the tubular member within the body. Amended independent claim 30, in turn, recites a medical assembly including at least one extracorporeal ultrasound transducer configured to direct an ultrasonic beam through the skin and into at least one inflatable member. Antecedent support for these amendments can be found, for example, in dependent claims 12 and 27 (now cancelled), and in Figures 7-9 and 11 of the drawings.

In contrast to independent claims 1 and 16, nothing in the *Daikuzono, Shturman*, and *Lipscher et al.* references disclose or suggest at least one extracorporeal ultrasound transducer for ultrasonically placing and monitoring the tubular member within the body. Furthermore, with respect to independent claim 30, nothing in the *Daikuzono, Shturman*, and *Lipscher et al.* references disclose or suggest at least one extracorporeal transducer configured to direct an ultrasonic beam through the skin and into at least one inflatable member. As discussed above, each of these references suggest the use of ultrasonic transducers coupled to the distal portion of a tube for emitting ultrasonic waves at a location within the body, and are thus not extracorporeal, as recited in each of claims 1, 16, and 30. Accordingly, Applicants respectfully assert that the cited prior art reference fail to disclose each and every element of these claims.

With respect to the rejection of independent method claims 31, 40, 47, and 48, Applicant further asserts that the cited prior art references also fail to disclose or suggest each and every element of these claims. Claim 31, 40, and 47 each recite, among other novel elements, the steps of providing at least one ultrasonic transducer on the anterior surface of a patient's neck. Claim 48, in turn, recites the step of providing at least one ultrasonic transducer located outside of the patient's body. Claims 31, 40, and 47-48 each recite other novel claim limitations, including the step of inflating a leader balloon cuff with an acoustically transmissive material, which as is discussed on page 19, cols. 12-20 of the Application, can be used to increase the transmission of ultrasound waves through the leader balloon cuff.

As discussed above, neither *Daikuzono* nor *Shturman* disclose or suggest the use of an ultrasonic transducer located on the anterior surface of a patient's neck or outside of

the patient's body. While the *Lipscher et al.* reference does suggest an ultrasonic transducer means outside of the patient's body, this reference fails to disclose or suggest other claimed limitations, including the step of inflating a leader cuff balloon with an acoustically transmissive material. Accordingly, Applicant respectfully submits that the cited prior art references fail to disclose each and every element of independent claims 31, 40 and 47-48.

Because independent claims 1, 16, 31, and 40 are allowable, Applicant further asserts that dependent claims 2-11, 13-15, 17-26, 28-29, 31-39, and 41-46 are also allowable for at least the reasons provided above and since they contain other significant limitations not disclosed or suggested by the cited prior art.

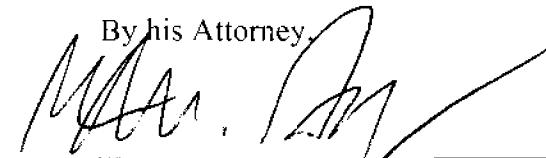
With this Amendment, newly presented claims 49-55 have been added, which Applicant respectfully submits are also patentable over the cited prior art references. In particular, newly presented independent claims 49 and 55 each recites, among other novel elements, at least one extracorporeal ultrasound transducer configured to direct an ultrasonic beam into a patient's body.

Reexamination and reconsideration are respectfully requested. It is respectfully submitted that the claims are now in condition for allowance; issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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By his Attorney



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